INTRODUCTION

Hallux abducto valgus (HAV) or bunion deformity, as it is commonly known, affects many people around the world. Many authors agree that biomechanics of the foot play a major role in acquiring this deformity (1-5). Management of the deformity starts by stabilizing the foot to prevent any progression from occurring (2). There are different conservative treatment options for managing HAV deformities (5, 6), however, if pain persists in spite of conservative treatment, then surgical procedures are indicated.

Over 100 different osteotomy techniques have been described for the correction of hallux abducto valgus deformities (1, 5, 7). The correction of the HAV deformity using the Mini TightRope system has been around for many years. This technique uses no osteotomy to reduce the intermetatarsal angle between the first and second metatarsals (7-9). The benefits of using the Mini TightRope system are decreased postoperative pain and disability and the elimination of the inherent risks that are associated with an osteotomy (7, 10, 11). In a 2010 study by Shi et al, the authors demonstrated that when the Mini TightRope system was compared to a distal osteotomy for the correction of hallux abducto valgus, both groups showed reduction in the intermetatarsal angle, hallux abducto angle, sesamoid position, metatarsal protrusion, and Seiberg’s Index postoperatively (7).

Many other studies have shown that the Mini TightRope system is effective in correcting bunion deformities (7, 8, 10-13). The Mini TightRope system has not been a popular technique due to high complication rates. The most reported complication with the system is fracture through the tunnel placed in the second metatarsal (7, 10, 12, 14, 15). Shi et al reported a 33% fracture rate in their Mini TightRope group (7). We believe the reason the Mini-TightRope system has had such a high fracture rate through the second metatarsal is due to placing the tunnel for the tightrope in the weak diaphysial aspect of the metatarsal (7, 10, 13, 14, 16). All previous studies on the Mini TightRope system have placed the device in the midshaft of the second metatarsal causing the high percentage of fracture associated with the device.

A study performed by the Arthrex research and development team looked to see if altering the tunnel placement in the second metatarsal would result in the ultimate strength of the second metatarsal (17). In the Arthrex study they compared the strength of a tunnel placed 45 mm from the distal tip of the second metatarsal to a tunnel placed 25 mm from the distal tip. The researchers found that the distally-placed tunnel in the second metatarsal results in a greater ultimate load on the second metatarsal.

The purpose of this study is to demonstrate that a tunnel placed in the second metatarsal head using the Arthrex Mini TightRope system, will have greater ultimate load to failure and less incidence of second metatarsal fractures when compared to a tunnel placed 25 mm proximal to the head of the second metatarsal due to greater ultimate strength of metatarsal head compared to the weaker diaphysial bone in the shaft (17). If the tunnel placed in the head of the second metatarsal shows greater strength and less incidence of second metatarsal fracture then using the Mini TightRope system from the first metatarsal head to the second metatarsal head would be a better choice for the correction of HAV deformities and would lead to fewer incidences of second metatarsal fractures (Figure 1).
METHODS

For our study we received approval from Scripps Health Institutional Review Board. The study was made possible by a grant provided by the Scripps Clinic Medical Group. A total of 9 unpaired fresh-frozen cadavers were used from 8 men and 1 woman, ages ranging from 24 to 70 years (mean 50.2 years). Although cause of death of the specimens was not known, only specimens that had no rheumatologic diseases or history of osteoporosis were used in the study.

The specimens were randomly divided into 2 groups to receive either a distal or proximal TightRope placement. For the distal fixation the TightRope was placed from the lateral epicondyle of the second metatarsal in an oblique fashion to the diaphysis-metaphysis junction of the first metatarsal. For the proximal fixation the TightRope was placed 25 mm proximal to the second metatarsal head in a straight transverse fashion to the first metatarsal shaft. Care was taken to place the Mini TightRope equidistant from dorsal and plantar aspect of the second metatarsal. The TightRope system was surgically placed as it would in surgery.

Each specimen was dissected to isolate the first, second, and third metatarsals with their corresponding cuneiforms and the navicular with all ligamentous soft tissue preserved. The specimen was then fixated on the dorsal surface of the second metatarsal to a custom-built plate with one 6 mm screw through the middle cuneiform, The plate was positioned in such a way that would not allow dorsiflexion of the second metatarsal. To prevent rotational motion of the second metatarsal on the plate, a zip tie was used to tie it to the plate while allowing the first metatarsal to go through its full independent range of motion. The specimen with custom plate was then attached to the Instron 8511 material-testing machine. The specimen was positioned on the Instron machine to provide a superior to inferior load from the machine to act as ground reactive forces dorsiflexing the first metatarsal. A 500 cycle of 100N/sec was applied to the first metatarsal head to test the ligamentous attachments of the specimen and to determine if there was a fatigue failure of the second metatarsal or the fixation.

Once the cyclical loading part of the experiment was completed, the first metatarsal was loaded, dorsiflexing the first ray to test the fixation to failure. The experiment was stopped when the fixation failed, any of the metatarsals fractured, or if the specimen failed proximally at any of the joints. Data were collected through Microsoft Excel and analyzed. After the conclusion of the load to failure portion of the experiment each specimen was carefully examined to determine the method of failure (Figure 2).

RESULTS

One proximal fixation specimen (specimen 6) failed at the first metatarsal-cuneiform joint after 10 cycles of 100N/sec due to aggressive dissection of ligamentous attachments at the joint and was omitted from the study. The mean failure load of the distal second metatarsal fixations was 572.045 N ±96.6 compared to 460.61 N ±114.2 for the proximal shaft fixations. Table 1 shows failure loads and methods of failure of each sample. Figure 1 show the ultimate load to failure of proximal fixation specimens to the distal fixation when paired.

Overall the specimens with distal fixation had 114.44 N more ultimate strength of failure; however this was not statistically significant. There was no fracture of the second metatarsal in the distal fixation group compared to 3 out of 4 proximal fixation groups exhibiting second metatarsal fractures as the method of failure (P = 0.02) (Figure 3).

DISCUSSION

Our study did not show any statistical significance in the ultimate load to failure of the second metatarsal TightRope fixation based on the placement of the fixation distally versus proximally, however we did exhibit statistically significant second metatarsal fractures in the proximal fixation group, 3 out 4 (75%) of the specimens fractured, compared to no fractures in the distal fixation group (P = 0.02). Our results were comparable to other studies in that placing the TightRope device in the second metatarsal shaft would result in increased risk of fracturing (7, 10, 12, 14-16, 18).

Correction of hallux valgus deformity is one of the more complicated procedures performed in foot surgery due to all the variables involved in the deformity. There
are many different procedures that can be used to correct a hallux valgus deformity that utilizes an osteotomy of the metatarsal or fusion of metatarsal cuneiform joint (4, 19). Each type of procedure comes with its own set of complications, which include soft tissue infection, fracture through osteotomy site, avascular necrosis, hallux varus, recurrent hallux valgus, nonunion, fixation failure and pain. There is no one correct procedure to fix hallux valgus deformity; instead the procedure chosen is based on the patient, type of correction, and amount of correction needed (5,16). For our modified tightrope procedure there are some factors that the senior author considers in patient selection.

The deformity has to be flexible, which can be tested clinically by manually being able to shift the first metatarsal over laterally. One of the reasons HAV deformity develops is due to intrinsic weakened ligamentous attachments to the first metatarsal head leading to medial displacement of the first metatarsal head causing instability at the first metatarsal cuneiform joint (2, 3). According to Perrera et al as the medial supporting structures on the first metatarsal fail, the metatarsal head can then drift medially, slipping off the sesamoid apparatus. As the metatarsal moves medially the deep transverse metatarsal ligament and adductor hallucis becomes dysfunctional as its medial and plantar attachment rotates inferiorly as a deforming force (2). By using a Mini TightRope fixation, we are able to bring the first metatarsal head to a correct position and prevent it from migrating out of alignment, which in turn leads to stability at the first metatarsal cuneiform joint and neutralizes the deforming forces acting on the first metatarsal. The tightrope procedure avoids an osteotomy or fusion of a joint and avoids the complications associated with these procedures (7). The use of a Mini TightRope is not without any complications; in fact, the procedure lost its utilizations after several studies have shown high complication rate of second metatarsal fracture (7, 10, 14, 16).

In our study, we demonstrated that placing the TightRope at the second metatarsal head instead of the shaft resulted in no fractures of the second metatarsal. The senior author has performed over 100 distal fixation Mini TightRope procedures for the correction of HAV deformities with no incidence of second metatarsal fracture in a 5-year period. In our current study, the ultimate load to failure of the modified distal fixation was 114.45 N more than the fixation method proposed by the Arthrex Research and Development team (17), although there was no statistically significant difference between the ultimate load to failure of the two fixation methods due to small sample size. Studies looking at the ultimate strength of the second metatarsal and its weakest point leading to failure have shown that the midshaft of the second metatarsal is its weakest point leading to increased risk of fractures and stress fractures (20, 21).

We can infer from the results of our study and previous studies that placing the TightRope at the second metatarsal head would have an even higher ultimate load to failure than the traditional mid-shaft placement, even though we were able to find statistically significant results in the ultimate load to failure with tunnel placement. To our knowledge there has been no studies demonstrating the ultimate strength of the second metatarsal head or epicondyle. Muehleman et al demonstrated that the mean load to failure of the second metatarsal was 218.8 N and the point of failure for all of their specimens was in the shaft (20). In the current study our mean failure load was 534 N, which is expected to be higher due to preservation of the corresponding tarso-metatarsal joints, which we believe by doing so we demonstrated a more physiological testing of the metatarsals.

When the TightRope device is placed between the
first and second metatarsals the two metatarsals have a dependent range of motion, and generally go through range of motion as a unit. As the first metatarsal goes through its range of motion during gait, it will move the fixed second metatarsal along with it, causing increased stress on the second metatarsal. By putting the TightRope in the second metatarsal shaft, we weaken the already weak avascular diaphysial bone. With the increased load added to the second metatarsal from the more mobile first metatarsal, this will lead to fracturing of the second metatarsal as was demonstrated in our study and reported in previous clinical studies (1,7,10,12, 14). Placing the TightRope at the second metatarsal head will allow stronger vascular metaphyseal bone to withstand deforming forces that would otherwise lead to fracturing of the metatarsal.

Our study was not without any weakness. First the study was performed on limited cadaveric specimens that were stripped of most soft tissue attachments and only part of the forefoot and midfoot was used. We tried to preserve as much soft tissue attachments that would provide us with the most accurate physiological scenario but in order to isolate the fixation as it is placed in the first and second metatarsal, such sacrifice was necessary.

Having a small sample of specimens led to a lower power study making it difficult to achieve statistically significant results in the ultimate strength of the second metatarsal as it was hoped before we conducted the study.

The next limitation of our study was the axial loading of the first metatarsal to failure while the rest of the specimen was fixed, which is not the case in real life gait cycle because the foot is a dynamic structure. We tested the load to failure of the specimens in a one-dimensional model, as we know the first ray range motion is tri-planar. By preserving the joints proximal to our fixation we tried to allow for some of the tri-plane motion of the first ray as it was loaded, as it was demonstrated in our higher ultimate load to failure of the second metatarsal compared to previous studies (17, 20, 21). None of our specimens demonstrated a HAV deformity. In a pathologic metatarsal varus deformity, the first metatarsal tries to deviates medially in the transverse plane as the TightRope holds it in place, causing increased load on the second metatarsal. We were not able to recreate this transverse plane force in our study due to not having the equipment to do so.

Lastly we only cyclically loaded the specimens for 500 cycles as opposed to cyclically loading to failure, which should be tested in future studies, because as the fixation is loaded constantly by a patient throughout their daily activities the TightRope device is at risk of fatigued failure. It would be beneficial to demonstrate if the cyclical loading of the proximal fixation with the more distal fixation would lead to higher incidence of second metatarsal fracture, however this is difficult to study in cadaveric specimens as opposed to live bone, which has repair and remodeling properties.

To our knowledge, there have been no other studies demonstrating the placement of the TightRope device in the second metatarsal head leading to fewer complications of second metatarsal fractures. This study should provide some insight to this new technique to allow surgeons to utilize the Mini TightRope procedure in correcting HAV deformity while avoiding the previous high complication rates of second metatarsal fractures.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Fixation Type</th>
<th>Age</th>
<th>Sex</th>
<th>Method of Failure</th>
<th>Failure Load (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Proximal</td>
<td>24</td>
<td>M</td>
<td>Fixation (fiber wire) broke no damage to 2nd metatarsal</td>
<td>530.93</td>
</tr>
<tr>
<td>2</td>
<td>Distal</td>
<td>24</td>
<td>M</td>
<td>Fixation pulled through 2nd metatarsal no damage to bone</td>
<td>602.84</td>
</tr>
<tr>
<td>3</td>
<td>Proximal</td>
<td>40</td>
<td>M</td>
<td>Fracture through 2nd metatarsal tunnel</td>
<td>594.448</td>
</tr>
<tr>
<td>4</td>
<td>Proximal</td>
<td>40</td>
<td>M</td>
<td>Fracture through 2nd metatarsal proximal to tunnel</td>
<td>326.765</td>
</tr>
<tr>
<td>5</td>
<td>Distal</td>
<td>68</td>
<td>M</td>
<td>Failure at tarso metatarsal joint, 2nd metatarsal intact</td>
<td>407.475</td>
</tr>
<tr>
<td>6</td>
<td>Proximal</td>
<td>69</td>
<td>F</td>
<td>Failure at TMTJ after cyclical loading</td>
<td>Omitted</td>
</tr>
<tr>
<td>7</td>
<td>Proximal</td>
<td>69</td>
<td>M</td>
<td>Failure of 1st metatarsal base and failure at TMTJ, no fracture of 2nd metatarsal</td>
<td>651.879</td>
</tr>
<tr>
<td>8</td>
<td>Distal</td>
<td>70</td>
<td>M</td>
<td>Failure at TMTJ, Fixation on 1st metatarsal pulled plantarly, no fracture of 2nd metatarsal</td>
<td>625.986</td>
</tr>
<tr>
<td>9</td>
<td>Proximal</td>
<td>48</td>
<td>M</td>
<td>Fracture of dorsal cortex of 2nd met tunnel, Fracture at 1st TMTJ and base of 1st met</td>
<td>633.67</td>
</tr>
</tbody>
</table>